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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,820	04/22/2002	Michael Blind	BOH6278P0020US	5434

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
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EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

94.

Office Action Summary	Application No.	Applicant(s)	
	09/937,820	BLIND ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-35* is/are pending in the application.

4a) Of the above claim(s) *30-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-29* is/are rejected.

7)☒ Claim(s) *22-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I claims 18-29 in the reply filed on 22 July 2004 is acknowledged.

Claims 30-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

2. Claims 22-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

3. Claim 22 is objected to because of the following informalities: In line 2 of claim 22 "nucleic" is misspelled. Claim 26 is objected to because of the following informalities: In line 5 of claim 26 "promoter" is misspelled. Claim 29 is objected to because of the following informalities: In line 2 of claim 29 "promoter" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Barber et al. (WO 98/32880 07/30/1998).

Barber et al. teach a method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target by (a) preparing a candidate intramer mixture of nucleic acids, (b) contacting the candidate intramer mixture of nucleic acids with the intracellular target or part thereof, (c) selecting and isolating nucleic acids with an increased affinity to the target reactive to the candidate intramer mixture, (d) reverse transcribing, if the candidate mixture comprises RNAs, and amplifying the nucleic acids obtained in step (c), (e) optionally repeating the aforementioned steps (b-d), (f) isolating and sequencing the clones (intramers) obtained in step (e), testing the expression product of the insert of the clone in step (f) binds to and affects the function of the intracellular target *in vivo* (see whole document, specifically p5 paragraph 2). They also teach a cytoplasmic expression system for the testing step (g) (see p. 27 paragraph 2 and 3). They further teach mapping the binding site of the intamer to the target (see p. 5 paragraph 1). Barber et al. teach a method for the identification of a functional intracellular target associated with a particular phenotype and the corresponding intramer capable of binding to and modifying the function of said target, by (a) preparing a candidate intramer mixture of nucleic acids, (b) cloning the candidate intramer mixture of nucleic acids under the control of a suitable promoter in a vector optionally containing a selectable marker, (c) introducing the vector obtained in step (b0 into a reporter cell line allowing the positive or negative phenotype selection, (d) selecting the cells with a n altered phenotype, (e) determining the sequence of the nucleic acid inserted in the vector of step (b) intramer and the compound to which it binds (see p. 4 paragraph 2). They teach the candidate intramer mixture of nucleic acids comprises single stranded nucleic acids (see p. 15 paragraph 4). They further teach RNA as a single stranded nucleic acid (see p. 15 paragraph 4). They teach the reporter cell

line of step (c) allows negative selection (see p. 32 paragraph 3). They teach the reporter cell line contains a vector with a selectable marker and a reporter gene encoding a toxin under the control of an inducible promoter wherein only cells will survive that express the vector of step (b) which express a nucleic acid (intramer) inhibiting a compound which is required for the activation of the promoter controlling the toxin gene, wherein step (d) the surviving cells are selected (see p. 32 paragraph 3, p. 49 paragraph 2). They further teach the candidate intramer mixture of nucleic acids of the vector step (b) is under control of a Pol III promoter (see p. 16 paragraphs 2 and 3, p. 35 paragraph 2). They additionally teach the toxin gene is HSV-thymidine-kinase (see p. 32 paragraph 32).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (WO 98/32880 07/30/1998) in view of Kolanus et al. (*Cell*, July 26, 1996).

The teachings of Barber et al. are described previously.

Barber et al. do not teach the functional intracellular target is an integrin.

Kolanus et al. teach integrin as a functional intracellular target (see whole document, specifically the abstract)

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Kolanus's integrin with Barber's method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target in order to evaluate the effect (s) of inactivating integrin in a cellular system. Kolanus et al. state that the characterization of the cellular

components required to regulate integrins is of particular interest (p. 234, col. 1 first paragraph). It would have been prima facie obvious to apply Kolanus's integrin to Barber's method for the identification of an intramer to achieve the expected advantage of evaluating the effects of integrin inactivation in a cellular system.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (WO 98/32880 07/30/1998) in view of Clackson et al. (USPN 6,649,595 B2 11/18/2003).

The teachings of Barber et al. are described previously.

Barber et al. do not teach an IL-2 promoter to drive gene expression.

Clackson et al. teach an IL-2 promoter to drive gene expression (see col. 115 lines 51-60).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Clackson's IL-2 promoter with Barber's method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target in order to evaluate the effect (s) of the toxin gene expression controlled by the IL-2 promoter in a cellular system. The IL-2 promoter is very well known in the art and it would have been prima facie obvious to apply Clackson's IL-2 promoter to Barber's method for the identification of an intramer to achieve the expected advantage of having toxin gene expression controlled by the IL-2 promoter.

Summary

7. No claims are free of the prior art and therefor were not allowed.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail

system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/4/04